

REMARKS

This amendment is being filed in conjunction with a Request for Continued Examination and includes a request for 1-month extension of time.

Original claims 1-7 and 9-11 have been canceled. Claim 8 remains pending.

New claims 12-32 have been added. These new claims are based on claims 1-7 and 9-21 of U.S. Patent 7,521,459 to Baumann et al., filed July 28, 2003 and issued April 21, 2009. These new claims have also been copied into Applicants' co-pending application 12/425,961.

For the reasons indicated previously, we believe that claim 8 is patentable. Those reasons are reiterated as follows.

§ 112, 1st Paragraph, Rejection

Claim 8, in its original form as filed, is among the group of claims (2, 3 and 6-11) rejected under 35 USC 112, 1st paragraph, for allegedly failing to comply with the written description requirement. Applicants respectfully submit, however, that claim 8 as originally filed and as amended does fully comply with the written description requirement. Claim 8 as amended reads:

8. A method of visibly reducing a human skin wrinkle comprising:
topically applying to the human skin wrinkle an IRM compound that is an agonist of TLR7, TLR8, or both TLR7 and TLR8 in an amount and for a period of time sufficient to visibly reduce the wrinkle; wherein the IRM compound is an imidazoquinoline amine, a tetrahydroimidazoquinoline amine, an imidazopyridine amine, a 1,2-bridged imidazoquinoline amine, a 6,7-fused cycloalkylimidazopyridine amine, an imidazonaphthyridine amine, a tetrahydroimidazonaphthyridine amine, an oxazoloquinoline amine, a thiazoloquinoline amine, an oxazolopyridine amine, a thiazolopyridine amine, an oxazolophthyridine amine, a thiazolonaphthyridine amine, or a combination thereof.

According to MPEP 2163 I.A., first sentence, "There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed." It is clear that the inventors had possession of the claimed invention as defined by claim 8. While the Office Action correctly notes that additional work would be required to practice the claimed invention for a given IRM compound class, that goes to primarily to the question of enablement

and not written description. Further, as to enablement, the amount of work necessary to practice the invention of claim 8 would not require “undue experimentation.”

It may also be worth noting that claim 8 expressly requires “topical” administration of the IRM compound. Claim 4, directed to topical administration, was not subject to a written description rejection.

The compound classes listed in claim 8 (as originally filed) are also expressly described at page 2, line 30, to page 3, line 3, of the specification. Many examples within the TLR 7 and/or 8 agonist IRM compound classes listed in claim 8 are disclosed in the patent applications listed in the paragraph bridging pages 3-4 of the specification. One skilled in the art would readily understand that such compounds operate through a common TLR 7 and/or 8 mechanism and how to formulate such compounds for topical administration. Examples of topical formulations can be found in disclosures of the patent documents referenced on page 7, last paragraph, of the specification. The disclosures of the patent documents reference are all incorporated by reference in the present application (see page 18, lines 4-6). The present application disclosure provides clear direction to one skilled in the art as to how to practice the claimed invention—i.e., apply a topical preparation of one of the claimed IRM compounds--and is not merely a “hunting license.”

Accordingly, it is requested that the rejection under 35 USC 112, 1st paragraph, be withdrawn.

§ 103 Rejection

Claim 8 was rejected under 35 USC § 103(a) as being unpatentable over Yu et al. (US 6,335,023 B1) in view of Maibach et al. (US 2003/0072724 A1). Applicants respectfully traverse on several bases.

First, Yu et al. does not teach or suggest whatsoever using imiquimod to treat wrinkles or for any age-related condition. Imiquimod is merely in a large laundry list of known drugs that Yu et al. suggests may be combined with the drugs (oligosaccharide aldonic acids) that Yu et al. teaches for age-related dermatological disorders. The inclusion of imiquimod in certain claims is exactly the same.

Second, Maibach et al. does not remedy the deficiencies of Yu et al. because Maibach et al. merely discloses that imiquimod is a treatment for warts – not wrinkles. It actually appears that paragraph 0092 of Maibach et al. may be an erroneous inclusion, since it appears to have no relevance to the rest of the disclosure and the following paragraph 0095 has the same heading “Active Ingredients” and address hyperpigmentation. In any case, one skilled in the art would certainly not read Maibach et al. as suggesting use of imiquimod for treating wrinkles where it is very clear that Maibach et al. is listing imiquimod as a wart treatment.

Third, even if one were to accept Yu et al. as suggesting imiquimod for treating some age-related dermatological disorders, and Maibach et al. as treating hyperpigmentation, the combination still would not have taught use of imiquimod to treat wrinkles per se.

Accordingly, it is submitted that the rejection of claim 8 under 35 USC § 103(a) should be withdrawn.

Respectfully submitted,

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